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ORIGINAL ARTICLE

Risk factors leading to midurethral sling revision: a multicenter case-control study

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Abstract
Introduction and hypothesis To determine risk factors for sling revision after midurethral sling (MUS) placement.
Methods This multicenter case-control study included patients who underwent MUS placement and subsequent revision secondary to voiding dysfunction from January 1999–2007 from nine Urogynecology centers across the USA. Direct logistic regression analysis was used to determine which diagnostic variables predicted sling revision.
Results Of the patients, 197 met the study criteria. Patient demographics, urodynamic findings, and operative differences did not increase the risk for sling revision. Risk factors for sling revision did include: pre-existing voiding symptoms (OR 2.76, 95% CI 1.32–5.79; $p=0.004$) retropubic sling type (OR=2.28, 95% CI

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1.08–4.78; $p=0.04$) and concurrent surgery (OR=4.88, 95% CI 2.16–11.05; $p<0.001$)
Conclusions This study determined that pre-existing obstructive voiding symptoms, retropubic sling type, and concurrent surgery at the time of sling placement are risk factors for sling revision.

Keywords Voiding dysfucntion · Midurethral sling · Sling revision

Introduction

Iatrogenic post-operative voiding dysfunction is a well-recognized complication of any surgical procedure used to treat stress urinary incontinence that decreases patient satisfaction and quality of life [1]. The SISTEr trial found that voiding dysfunction occurred in 2% of patients following Burch colposuspension and 14% ($p<0.001$) following rectus fascia pubovaginal sling [2]. The retropubic tension-free vaginal tape (TVT) midurethral sling procedure [3] is now one of the most commonly performed procedures to treat stress urinary incontinence with return to normal voiding function occurring more quickly than with traditional continence procedures [4]. The reported incidence of short-term post-operative voiding dysfunction following the retropubic midurethral sling ranges from 2.5% to 60% with an overall incidence of 20.2% [5]. Long-term retention requiring surgical treatment following TVT reportedly occurs in 1.9–4% of cases [6, 7]. Evolving management of stress incontinence has led to the trans-obturator approach for midurethral sling placement with the potential to further decrease associated complications including incidence of voiding dysfunction [5, 8].

Better prediction of post-operative voiding dysfunction and/or urinary retention following midurethral sling (MUS) surgery would allow clinicians the opportunity for improved preoperative counseling and could alter treatment selection [9]. The identification of patients at risk for post-operative voiding dysfunction remains a clinical challenge. Despite multiple demographic, clinical, urodynamic, and surgical variables suggested to have diagnostic value in predicting voiding function following traditional continence procedures [10-13] or synthetic midurethral slings [14-18], none have been consistently reproduced in various studies or universally accepted as reliable predictors. Furthermore, it has not been determined if different surgical techniques of synthetic midurethral sling tensioning intraoperatively (cough/credé maneuvers versus visual placement) predict post-operative voiding function.

Therefore, The Fellows' Pelvic Research Network [19] designed a multicenter case-control study to assess risk factors for surgical sling revision secondary to voiding dysfunction following synthetic MUS placement.

Materials and methods

Study design

We conducted a multicenter case-control study of women who underwent midurethral polypropylene sling placement and subsequent sling revision secondary to voiding dysfunction between January 1999 and January 2007. After Institutional Review Board approval at nine US Urogynecology centers, charts were reviewed. Eligible cases were identified by using Current Procedural Terminology (CPT) codes (57287, removal/revision of sling and 53500, urethrolysis). Control patients were identified by using CPT code 57288 (sling operation for stress incontinence). Each case was matched to two controls who underwent midurethral polypropylene sling placement and did not require sling revision. Controls were matched by age (within 10 years) and date of surgery (within 3 months).

Data extracted included patient characteristics, urodynamic data, pre-operative clinical course, sling type, and operative data. Patient characteristics and pre-operative clinical data analyzed included age, race, body mass index, parity, smoking status, menopausal status and estrogen use, diagnosis of chronic obstructive pulmonary disease or asthma, previous hysterectomy, previous surgery for prolapse or incontinence, pre-operative obstructive voiding symptoms by history (hesitancy, slow stream, intermittent flow, incomplete emptying, retention-void <25 mL), post-void residual volume (PVR), stage of prolapse, and urodynamic parameters including: intrinsic sphincter deficiency (ISD; defined by maximum urethral pressure (MUCP) <20 or leak point pressures (LPP) <60), maximum detrusor pressure (Max pdet), maximum flow rate, voiding time, volume at first sensation of bladder filling, and maximum cystometric capacity. The type of sling used was categorized as retropubic or trans-obturator. Sling brand information was also collected. Data collected from the sling surgery included pre-operative diagnosis of incontinence or reason for sling placement (stress urinary incontinence (SUI), MUI, OAB, prophylactic placement), training background of surgeon who performed sling (gynecologist, urogynecologist, urologist), concomitant procedures, complications (cystotomy, urethrotomy, and blood loss greater than 500 ml), type of anesthesia, and method of sling tensioning (cough stress test, credé maneuver, visually set).

Statistical analysis

Analyses were carried out using SAS (SAS Institute, Inc., Cary, NC, USA) and SPSS (SPSS, Inc., Chicago, IL, USA). Direct logistic regression was conducted to determine which diagnostic variables predicted group status (sling revision versus no sling revision) after adjusting for the other variables. Univariate analyses at $p \leq 0.10$ identified the pre-sling predictors to include in the logistic regression model, based on chi-square tests for categorical variables, independent samples *t* tests for normally distributed continuous variables, and Mann-Whitney rank sums tests for non-normally distributed continuous variables. For the multivariate analysis, *$p \leq 0.05$ denoted statistical significance.*

Results

During the study period, 197 patients met case study criteria and underwent sling revision; 394 women were matched as controls. Cases or controls were excluded if the sling material was other than polypropylene, was not placed at the mid urethra, no pre-operative and post-operative data were available, if patients had a history of multiple sclerosis, Parkinson's disease or other neuropathic bladder disorder, or underwent revision for reason other than voiding dysfunction such as isolated mesh erosion. The two groups were similar in parity, race, smoking status, menopausal status, hormone use, incidence of obstructive airway disease, and history of previous prolapse and incontinence surgery (Table 1). Controls had greater average BMI than cases at 29.7±6.3 versus 28±6.6 ($p=0.014$).

The two groups did not differ by diagnosis prior to sling placement ($p=0.09$; Table 1). ISD diagnosis, defined by LPP less than 60 and/or MUCP less than 20, did not differ between groups. Obstructive voiding symptoms were assessed prior to sling placement including: hesitancy, slow or intermittent urine stream, incomplete emptying, and urinary retention (void <25 cc). One hundred and seventy case patients had this data available via chart review (76.1%) as compared to 384 (98.7%) controls. Significantly more patients complained of obstructive voiding symptoms before sling placement in the study group as opposed to controls ($p=0.022$). The most common voiding complaint was of incomplete bladder emptying with 36 patients (24%) with this documented subjectively as a patient complaint in their records.

More controls underwent uroflowmetry or urodynamics prior to sling placement. The PVR before sling placement was statistically higher in the study group with a mean of 72 mL versus 43 mL in controls ($p=0.018$). Of those patients who had urodynamics or uroflowmetry performed, maximum detrusor pressure (Pdet) and maximum urine flow rate (Qmax) differed among groups with a higher Max Pdet in controls (35.5 cm H_2O vs. 42.3 cm H_2O; $p=0.042$) and higher Qmax in the cases (25.1 ml/s vs. 22.4 ml/s; $p=0.044$). Voiding time, volume at first sensation, and maximum cystometric capacity were similar between groups (Table 1).

In the sling revision group, 70.4% of the slings originally placed were retropubic slings and 29.6% were obturator slings (Table 1). This was similar to placement of slings in control patients with 39.3% of controls undergoing obturator slings and 60.3% retropubic slings ($p=0.058$). Sling brands were similar among cases and controls with the TVT (Ethicon: Somerville, NJ, USA) used most frequently among retropubic slings at 53.5% of cases and 46.5% of controls, and the TVT Obturator (Ethicon: Somerville, NJ, USA) for the most commonly placed obturator sling at 14.5% and 14.1%, respectively. Type of anesthesia did not differ between groups when comparing general anesthesia to local and/or regional anesthesia (68.6% vs. 60.3%; $p=0.059$). There was no difference in technique used for sling tensioning between groups when comparing cough/credé use versus visual cues ($p=0.64$), or with spacer use during sling tensioning ($p=0.18$).

Sling revision patients were more likely to undergo concurrent surgery when compared to controls (69.5% vs. 48.6%; $p<0.01$) with anterior colporrhaphy followed by posterior colporrhaphy, vault suspensions (uterosacral ligament suspension, sacrocolpopexy and sacrospinous ligament suspension), and hysterectomy most commonly performed.

Following elimination of missing predictor variable values, a total of 217/591 (36.7%) subjects (59 with sling revision, 158 without sling revision) were available for multivariate analysis. For the 217 patients with complete data for all predictors, testing of the full logistic regression model with all predictors in comparison with the constant-only (no predictors) model yielded statistically significant results, c^2 (9, $N=217$)=37.47, $p=<0.0001$. This finding indicates that the predictor variables taken together differentiate between subjects in the case versus control group. Pre-existing voiding dysfunction was found to be a significant predictor of sling revision after multivariate analysis was performed with an adjusted odds ratio of 2.76 95% CI 1.32-5.79 ($p=0.004$). Retropubic sling type was also found to be a significant predictor with an adjusted odds ratio of 2.28 95% CI 1.08-4.78 ($p=0.04$). Concurrent surgery was a predictor of sling revision with an adjusted OR of 4.88 95% CI 2.16-11.05 ($p<0.0001$). Despite initial differences found on univariate analysis ($p<0.10$), BMI, diagnosis, PVR, Pdet, Qmax, and anesthesia type were not significant predictors of sling revision when included in the multivariate analysis ($p>0.05$).

Table 1 Group comparison before and including sling placement

	Cases (*N*=197)	Controls (*N*=394)	Univariate analysis		Multivariate analysis	
			OR (95% CI)	*p* value	Adjusted OR (95% CI)	*p* value
Age (mean±SD; *N*=197, 389)	57.7 (±13.7)	57.1 (±13.0)		0.15		
BMI (mean±SD; *N*=185, 355)	28.3 (±6.6)	29.7 (±6.3)		0.014*	0.98 (0.93–1.04)	0.50
Parity (median/range; *N*=191, 384)	2 (0-11)	2 (0-9)		0.73		
Race (*N*=188, 360)						
Caucasian	164 (87.2%)	320 (88.9%)		0.83		
AA	8 (4.3%)	8 (2.2%)				
Hispanic	11 (5.9%)	26 (7.2%)				
Asian	2 (1.1%)	2 (0.6%)				
Other	3 (1.6%)	4 (1.1%)				
Smoker (*N*=194, 388)	23 (11.9%)	39 (10.1%)		0.51		
Menopausal (*N*=196, 387)	136 (69.4%)	253 (65.4%)		0.33		
Hormone use (*N*=193, 386)	46 (23.8%)	105 (27.2%)		0.25		
COPD/asthma (*N*=193, 383)	26 (13.5%)	31 (8.1%)		0.11		
Prior hysterectomy (N-196, 389)	84 (42.9%)	144 (37.0%)		0.23		
Prior POP surgery (*N*=196, 387)	34 (17.3%)	50 (12.9%)		0.38		
Prior SUI surgery (*N*=195, 386)	25 (12.8%)	39 (10.1%)		0.76		
Diagnosis (*N*=180, 391)						
SUI	108 (60.0%)	194 (49.6%)	1.50 (1.05-2.14)	0.09*	0.77 (0.38–1.58)	0.45
Other:	72 (40.0%)	194 (50.4%)				
MUI	58 (32.2%)	172 (44.0%)				
OAB	12 (6.7%)	18 (4.6%)				
prophylactic	2 (1.1%)	4 (1.0%)				
Voiding sxs present before sling (*N*=170, 384)	42 (24.7%)	63 (16.4%)	1.67 (1.08-2.60)	0.022*	2.76 (1.32–5.79)	0.004**
ISD (*N*=123, 311)	25 (20.3%)	55 (17.6%)		0.39		
Urodynamics or uroflow performed (*N*=160, 378)	121 (75.6%)	320 (84.7%)	0.56 (0.36-0.89)	0.013*		
PVR (mL) (*N*=134, 366)	71.8 (±102.1)	42.7 (±65.1)		0.018*	1.00 (0.99–1.00)	0.77
Max pdet (mmHg) (*N*=69, 183)	35.5 (±37.8)	42.3 (±36.9)		0.042*	1.00 (0.99–1.01)	0.67
Q max (mL/sec) (*N*=90, 277)	25.1 (±40.5)	22.4 (±20.5)		0.044*	1.01 (1.00–1.03)	0.16
Voiding time (sec) (*N*=74, 244)	53.3 (±46.1)	53.8 (± 42.8)		0.79		
Volume first sensation (mL) (*N*=102, 262)	144.3 (±102.7)	124.2 (±85.3)		0.14		
MCC (mL) (*N*=113, 288)	392.7 (±146.5)	380 (±126.5)		0.48		
Sling type (*N*=189, 389)						
Obturator	56 (29.6%)	153 (39.3%)	1.62 (1.12-2.34)	0.058*	2.28 (1.08–4.78)	0.04**
Retropubic	133 (70.4%)	236 (60.7%)				
Anesthesia (*N*=172, 390)						
Local/regional	54 (31.4%)	155 (39.7%)	1.44 (0.99-2.11)	0.059*	2.07 (0.65–6.55)	0.49
General	118 (68.6%)	235 (60.3%)				
Sling tensioning (*N*=160, 387)				0.64		
Cough/crede	50 (31.3%)	129 (33.3%)				
Visually	110 (68.7%)	258 (66.7%)				
Spacer used (*N*=160, 385)	101 (63.1%)	243 (63.1%)		0.18		
Concurrent surgery (*N*=190, 391)	132 (69.5%)	190 (48.6%)	2.38 (3.45-1.67)	<0.01*	4.88 (2.16–11.05)	<0.001**

OAB overactive bladder, *SUI* stress urinary incontinence

*$p<0.10$ for inclusion in multivariate analysis

**$p<0.05$ significant

Other factors investigated included intraoperative complications at the time of sling placement including cystotomy, urethrotomy, vaginal perforation, and estimated blood loss >500 mL. There was no difference in the incidence of complications at the time of sling placement between cases and controls overall (6% vs. 9%; $p=0.14$) and when compared individually. When comparing how many patients were sent home after their procedures with a catheter (either indwelling or intermittent self-catheterization), there was a significant difference found with more study patients discharged with catheters (71% vs. 29%; $p<0.001$).

Discussion

This multi-center case-control study examines an important clinical question, voiding dysfunction after midurethral slings. Although persistent postoperative voiding dysfunction is a relatively rare (1.9–6%) complication after midurethral sling placement, it is bothersome for patients and surgeons [6, 7, 20-22]. We used a discrete endpoint, surgical revision, to identify women with significant voiding dysfunction following their sling surgery and found that preoperative subjective voiding dysfunction, retropubic sling type, and concurrent surgery were predictors of need for sling revision. Because no universally accepted definition exists to define voiding dysfunction or postoperative urinary retention, and voiding symptoms often correlate poorly with urinary retention or elevated post void residual urine volumes [20, 21, 23-27], we felt that that a return to the operating room for voiding dysfunction would capture those cases where symptoms were significant.

Women frequently have concurrent abdominal or pelvic surgery at the time of midurethral sling placement. In our study, the odds of having concomitant surgery at the time of midurethral sling placement were nearly five times greater for the cases than the controls, suggesting that concomitant surgery is associated with increased voiding dysfunction. Although synthetic midurethral slings have been commonly used since the mid-1990s for treatment of stress urinary incontinence, most outcome studies do not include a large number of women who had concomitant prolapse surgery at the time of midurethral sling [20, 22, 28, 29]. In our study, 69% (132/197) of the cases and 49% (190/394) of the controls underwent a concurrent surgery, most commonly anterior and posterior colporrhaphy. The types of concomitant procedures noted in our study, predominantly anterior colporrhaphy, posterior colporrhaphy, hysterectomy, and vaginal vault suspension seem to be illustrative of the procedures most commonly performed concurrently with midurethral slings noted in the literature [20-22, 28, 29]. Most of these studies, however, are large case series [20, 21] or prospective cohort studies [25, 28] that are not designed to examine concurrent surgery as a risk factor for postoperative voiding dysfunction. Both our univariate and multivariate analyses show that concurrent surgery increases the odds of having postoperative voiding dysfunction. Perhaps anterior colporrhaphy makes the anterior vaginal wall less mobile and "fixes" the sling in an obstructive position, resulting in prolonged voiding dysfunction. The mechanism by which posterior colporrhaphy could contribute to postoperative voiding dysfunction is unclear. On the other hand, women with prolapse as well as incontinence may represent patients with more global pelvic floor damage where the underlying dysfunction is revealed postoperatively [30].

In addition, retropubic sling type was more commonly used in the cases (70%) than the controls (61%) and more than doubled the odds of postoperative voiding dysfunction. In a recent, multicenter, randomized controlled trial of TVT versus transobturator tape for the treatment of stress urinary incontinence, 6 week postoperative urinary retention occurred in 5.8% (5/85) in the TVT group and 2.6% (2/77) in the transobturator tape group [22]. Of note, only one sling release occurred over the 12-month postoperative follow-up, and this was in the TVT group. There was no significant difference in urge incontinence symptoms, as defined by an affirmative answer to "Do you experience urine leakage related to the felling of urgency" for either group. No other postoperative voiding parameters were included in the study.

Finally, the cases had 2.67 greater odds of experiencing obstructive voiding symptoms (hesitancy, slow stream/intermittent flow, incomplete emptying, and frank retention) prior to their initial midurethral sling surgery when compared with controls. This may indicate that these subjects have anatomic or other physiologic characteristics that predispose them to voiding dysfunction. Lukacz et al. addressed this question in a prospective cohort of 103 women undergoing either TVT alone or TVT and additional pelvic surgery [28]. Sixty-five of the subjects underwent both preoperative and postoperative evaluation of subjective voiding symptoms using the validated Urogenital Distress Inventory question "Do you experience and how much are you bothered by difficulty emptying your bladder?" Subjects' objective voiding symptoms were evaluated by PVR and voiding pressure-flow studies. Although the number of subjects included in the final analysis was small, Lukacz's study indicated that no significant change in subjective voiding occurred after TVT, although four subjects did report a worsening of voiding symptoms [28]. Our study seems to disagree with Lukacz's findings; however, this may be due to our more broad definition of voiding symptoms.

A multicenter, case-control study design is appropriate for addressing a rare outcome, such as voiding dysfunction after midurethral sling. The retrospective nature of our study creates several inherent limitations with data collection. Medical record data for many of the risk factor variables was incomplete or absent in both the case and control groups, and we did not use validated measures to collect these data. This poses a challenge when creating a logistic regression model, as the missing variables for several of the subjects cannot be included in the final model, and may have biased our results. On the other hand, in our final analyses, we were able to include 59 women with sling revision and nearly three times that number as controls which represents a large series of women with significant voiding dysfunction following their sling surgery.

In an effort to minimize biases inherent in this type of study design, each site investigator and the primary investigator conducted formal data monitoring at regular intervals. Missing variables for cases and controls were reconfirmed through each site investigator. Case and control definitions were standardized though CPT and ICD-9 codes in order to maximize the validity and reproducibility of the study. Confirmation of the correct diagnosis was confirmed through each subject's medical record. In an effort to control for confounders, we matched the cases and controls for potential confounders, such as age, date of surgery, and institution. Our exclusion criteria also attempted to control for history of neurologic conditions that may predispose one to postoperative voiding dysfunction. In addition, logistic regression analysis was performed to examine for potential confounders.

This case control study is an observational study design in which cases and controls derived from the same "source" population are compared to examine a rare outcome. The control group in a case control study provides the prevalence of exposure(s) in the population from which the cases are drawn and need to be sampled independent of the exposure(s). Selection bias, a systematic error that arises when the association between the exposure and disease, differs for those who did and did not participate in the study, is frequently present in retrospective case control studies. For example, patients can self-select by choosing to follow-up or not follow-up with the surgeon who has performed their initial midurethral sling surgery. Consequently, our control group may actually be composed of patients who chose to follow-up with an alternative physician when they actually had complications associated with voiding dysfunction that arose after their initial postoperative follow-up. Information bias, which is misclassification of the exposure, disease or other covariate, could also have been present. For example, controls may have been inappropriately classified as such due to a shorter follow-up period, consequently not allowing time for voiding dysfunction to develop. An attempt was made to control for this by reviewing all of the subject's postoperative clinic visit records.

While acknowledging that postoperative voiding dysfunction is a rare and usually ill-defined endpoint, comparing subjects who have undergone sling revision for such symptoms with those who have not provides the clinician with some risk factors that may be useful in preoperative counseling and decision making. The multicenter nature provides a degree of external validity that is lacking in many of the single center studies.

In conclusion, we found that pre-existing voiding dysfunction, retropubic sling type, and concurrent pelvic floor surgery independently increase the odds of postoperative voiding dysfunction necessitating surgical revision after placement of a mesh midurethral sling. Our findings suggests that we may indeed decrease the incidence of post-sling voiding dysfunction necessitating sling revision by not performing MUS incontinence procedures concurrently with prolapse repair procedures or in patients with preoperative obstructive voiding symptoms and perhaps should consider performing staged procedures. Although, thorough preoperative counseling with patients is recommended regarding the potential risk of sling revision versus the realistic implications of de novo or worsened SUI immediately after prolapse repair if choosing to delay sling placement. We may also need to take caution in widespread placement of retropubic slings by perhaps using a looser setting or restricting its use to those with ISD and considering obturator sling placement in those with preexisting obstructive or irritative voiding symptoms.

Conflicts of interest S. Molden, MD: Ethicon consultant/instructor
M. Murphy, MD, MSPH: Ethicon/AMS/Bard consultant/instructor
R. Rogers, MD: Pfizer research grant, NBC speaker's bureau/consultant.

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